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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,038	12/04/2001	Glenn R. Bowers	60116P1	2458

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,038

Applicant(s)

BOWERS ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-35 are pending.

Claim Objections

2. Claims 1-2, 15, 27 and 32 are objected to for the inclusion of a blank line where the ATCC Accession number should be.
3. Claims 5-14, 16-20, 23-24, 30-31, 33 and 35 are objected to because of the following informalities:

Claims 5-7 have an improper article before "plant" in line 2.

Claim 8 has an improper article before "plant".

Claims 9-13, 16, 18-20, 24 and 31 start with an improper article.

Claim 14 has an improper article before "soybean" in line 1 and "plant" in line 3.

Claim 17 has an improper article before "soybean" in line 3 and "plant" in line 5.

Claim 23 has an improper article before "soybean" in line 3.

In claim 30 --consisting-- should be inserted before "of" in line 2.

The colon after "of" in claims 33 and 35, line 3 should be deleted.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 7-13 and 21-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to soybean plants and methods of producing soybean plants that involve an indeterminate number of generations and parent plants or of introduced genes or transgenes of unknown function and number and not described in the specification, wherein it remains unclear what the identity of the plants in each of the steps would be, much less what the resultant product plant would be. Neither the plants required by each of the steps, nor the plants that are produced by the process are defined by genomic structure or by phenotypic characteristics, and therefore, the claimed invention lacks an adequate written description.

See *University of California v. Eli Lilly*, 119 F.3d 1567, 43 USPQ 2d 1405 (Fed. Cir. 1997), where it states:

[a] written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, and given the high level of unpredictability in this art, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

6. Claims 1-35 are rejected under 35 USC 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that Applicant intends to deposit seeds for S52-U3 at the ATCC, but there is no indication that the seeds have been deposited and there is no indication in the specification as to public availability. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1-2, 15, 27 and 32 are indefinite in their recitation of “ATCC Accession No. _____”, because the ATCC Accession No. is missing.

Claims 1, 27 and 31 are indefinite in its recitation of “soybean cultivar S52-U3”, claims 2, 15, 19-20, 27 and 32 are indefinite in its recitation of “cultivar S52-U3”, and claims 33-35 are indefinite in their recitation of “S52-U3-derived” and “S52-U3 traits”, given that a name does not clearly identify the claimed soybean cultivar and seed, and does not set forth the metes and bounds of the claimed invention. Since the name S52-U3 is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics that are associated with that denomination. In addition, the name appears to be arbitrary, and the specific characteristics associated therewith could be modified, as there is no written description of the soybean plant that encompasses all of its traits. Amending claims 1-2, 15, 27 and 32 to recite the ATCC deposit number would overcome the rejection.

Claim 6 is indefinite because it is unclear what physiological or morphological characteristics of the plant of claim 2 have been altered to produce the male sterile plant. Male sterility can be the result of many different physiological and/or morphological changes.

Claims 7 and 27, part (a), are indefinite in their recitation of “essentially all the physiological and morphological characteristics of a plant”. It is not clear which physiological and morphological characteristics of the plant are excluded.

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Claims 7 and 31 are indefinite in their recitation of a “one or more single gene transferred traits”, since it is unclear how many new traits the claimed plant would exhibit, and it remains unclear what the phenotype of the claimed plant would be.

Claim 9 is indefinite in its recitation of a soybean plant containing “one or more transgenes”, since it is unclear how many transgenes the claimed plant would have, and it remains unclear what the phenotype of the claimed plant would be.

Claims 10 and 12 lack antecedent basis for the limitation “said transgene” in line 1.

Claim 12 is indefinite in its recitation of “said transgene comprises a gene”. The transgenes of parent claim 9 have the transgene operably linked to one or more regulatory elements. However, a gene also has regulatory elements, as well as a coding region. It is unclear if Applicant intended that the transgene of claim 12 have at least two regulatory elements.

Claims 14-15 are indefinite in their recitation of “capable of expressing”. It is not clear if the plant actually does express all these characteristics. It is suggested that the phrase be replaced with --having--.

In claim 16, line 1, “the ... protoplasts” lacks proper antecedent basis, as none of claims 2 or 14 are drawn to protoplasts. Additionally, “being from a tissue” in lines 2-3 is awkward; to address this, it is suggested that --, wherein-- be inserted before “the cells” and “being” be replaced with --are--.

Claim 16 is indefinite because many of the members of the Markush group are not tissue types, but rather are cell types or organ types, and hence do not further define “tissue”.

Appropriate correction is required.

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Claim 16 not written in proper Markush format. The claims should be in the format “selected from the group consisting of A, B, C and D.” In line 2, “comprising” should be replaced with “--consisting--”. See MPEP § 2173.05(h).

Claims 18 and 24 lack antecedent basis for the limitation “said resultant seed” in line 2.

Claims 19-20, while not lacking antecedent basis for the limitation “said soybean plant of cultivar S52-U3” and “said plant of cultivar S52-U3”, are somewhat confusing because claim 17, upon which they directly depend, refers to “a soybean plant according to claim 2” and “a plant according to claim 2”. It would be less confusing to the reader if claim 17 and claims 19-20 used the same language.

Claim 27 lacks antecedent basis for the limitations “the plants of either soybean cultivar” in part (c) and “said emasculated plants of the cultivar” in part (e). Additionally, none of steps (c)-(e) of claim 27 use the plants grown from the seeds of the plants with the physiological and morphological characteristics of S52-U3, as such plants are not referred to as cultivars, and steps (c)-(e) refer to cultivars. It is also unclear which cultivar is being referred to in part (e).

Claim 28 lacks antecedent basis for the limitation “said hybrid soybean seed of claim 27” as claim 27 is drawn to a method.

Claim 29 is indefinite because there are no clear positive method steps. The method steps “employing the soybean plant” and “using the soybean plant” do not recite clearly defined positive method steps. It is uncertain for the recited breeding techniques what steps they would be comprised of, how many generations of crosses would be incorporated in the method, and what parent plants would be used for each cross.

Claim 30 lacks antecedent basis for the limitation “The soybean breeding program of claim 31” as claim 31 is drawn to a soybean plant.

In claim 30 it is unclear how many of the plant breeding techniques would be used and in what combinations. The method steps are not clearly defined. The claim it must recite clear positive method steps. For example, “recurrent selection” is not a method step. It is uncertain for the recited breeding techniques what steps they would be comprised of, how many generations of crosses would be incorporated in the method, what RFLPs or genetic markers are used, and what parent plants would be used for each cross.

Claim 31 is indefinite for its recitation of “single gene transferred traits comprise a gene”. A trait is a physiological or morphological characteristic. In this case it is caused by a single gene (as opposed to many), but it is not gene itself.

Claim 32 is indefinite because it is not clear what the other parent of the hybrid in part (a) is, it is not clear how inbred parent plants would be identified in part (c) or what they would be inbred parents of, and it is not clear what is pollinated in part (d).

In claim 32, part (d) it is unclear how controlling pollination can preserve homozygosity of a parent plant because pollination affects the progeny produced by the parent plant but does not alter the genome of the parent itself.

Claims 33 and 35 are indefinite in their recitation of “high yield potential”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

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Claims 33 and 35 are indefinite in their recitation of “a Relative Maturity rating of 5.2 (early MG V Maturity)”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 33 and 35 are indefinite in their recitation of “adaptation to the mid-South, the Southeast and to eastern Kansas/southwestern Missouri”, since the metes and bounds of these regions are not clearly defined and is subject to different interpretations, and given that is unclear what it means for the plant to be “adapted” to a region. The specification fails to define or clarify the use of these terms. Therefore, the characteristics of the claimed plant remain unclear.

Claims 33 and 35 are indefinite in their recitation of “moderate resistance”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 33 and 35 are indefinite in their recitation of “excellent emergence”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claims 33 and 35 are indefinite in their recitation of “excellent ... lodging resistance”, since this is a relative term, it is unclear how it is measured or what standard it is based on, and the specification fails to define or clarify the use of this term. Therefore, the characteristics of the claimed plant remain unclear.

Claim 34 lacks antecedent basis for the limitation "The method of claim 33" as claim 33 is drawn to a soybean plant.

In claim 34, part (b), the phrase "under plant growth conditions" is meaningless because Applicant has not defined appropriate plant growth conditions. The phrase should be deleted.

Claim 35 lacks antecedent basis for the limitation "The further S52-U3-derived soybean plant ... of claim 33".

Claim Rejections - 35 USC § 102 - 35 USC § 103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Rhodes (1999, US Patent 5,942,666).

The plants of the instant application, S52-U3, and the plants taught by Rhodes, 9392379521283, have the same traits including hilum color (buff), leaflet shape (ovate), pubescence color (gray), flower color (white), pod color (tan), plant habit (determinate), , Maturity Group (V), Round-Up resistance, and resistance to soybean cyst nematode races 3 and

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14, for example. The plants also share similar scores on traits that are affected by environment, *e.g.*, mean yield. Thus, the S52-U3 soybean plants were, and methods of their use, appear to be identical to the 9392379521283 plants and methods of their use.

Applicant has also claimed plants derived from S52-U3 soybean after an indeterminate number of generations of crosses and using unspecified second parents. In addition, some of the claims specify that at least two designated characteristics would be present in the claimed soybean. However, it appears that the claimed plants and seeds are the same as the prior art soybean cultivar 9392379521283, progeny of 9392379521283 or those plants transformed with transgenes, given that each has resistance to soybean cyst nematode and lodging resistance, for example. Alternatively, if the claimed plants and seeds of the instant invention are not identical to soybean cultivar 9392379521283, progeny of 9392379521283 or those plants transformed with transgenes, then it appears that 9392379521283, progeny of 9392379521283, and those plants transformed with transgenes only differ from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to S52-U3-derived plants. Similarly, the methods of crossing S52-U3-derived soybean would be the same as the methods of crossing prior art soybean cultivar 9392379521283 or progeny of 9392379521283. Thus, the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by 9392379521283 soybean plants progeny of 9392379521283 soybean plants and those plants transformed with transgenes.

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12. Claims 1-35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Luzzi (2000, US Patent 6,084,159).

The plants of the instant application, S52-U3, and the plants taught by Luzzi, 9524889614923, have the same traits including hilum color (buff), leaflet shape (ovate), pubescence color (gray), flower color (white), pod color (tan), plant habit (determinate), , Maturity Group (V), and Round-Up resistance, for example. The plants also share similar scores on traits that are affected by environment, *e.g.*, mean yield. Thus, the S52-U3 soybean plants, and methods of their use, appear to be identical to the 9524889614923 plants and methods of their use.

Applicant has also claimed plants derived from S52-U3 soybean after an indeterminate number of generations of crosses and using unspecified second parents. In addition, some of the claims specify that at least two designated characteristics would be present in the claimed soybean. However, it appears that the claimed plants and seeds are the same as the prior art soybean cultivar 9524889614923, progeny of 9524889614923 or those plants transformed with transgenes, given that each has high yield potential and lodging resistance, for example. Alternatively, if the claimed plants and seeds of the instant invention are not identical to 9524889614923, progeny of 9524889614923 or those plants transformed with transgenes, then it appears that 9524889614923, progeny of 9524889614923, and those plants transformed with transgenes only differ from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to S52-U3-derived plants. Similarly, the methods of crossing S52-U3-derived

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soybean would be the same as the methods of crossing prior art soybean cultivar 9524889614923 or progeny of 9524889614923. Thus, the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by 9524889614923 soybean plant, progeny of 9524889614923 soybean plants and those plants transformed with transgenes.

Conclusion

13. No claim is allowed.

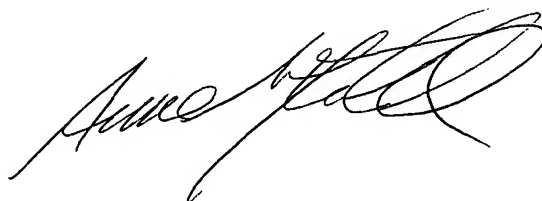
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.

March 31, 2003

A handwritten signature in black ink, appearing to read "Anne R. Kubelik", with a stylized, flowing script.